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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,075	WIETING ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-16 and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant sets forth in claims 1, 24, and 30 that the diameter of the chamber of the invention is "approximately" constant in the region between the blood inlet port and the blood outlet port. Applicant does not support this limitation in the specification, and the drawings illustrate that the diameter of the chamber is actually constant between the blood inlet and blood outlet. The specification and figures do not support the broader claim limitation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "means for directly impelling... to a higher rotational rate than is possible by tangentially injecting blood into the chamber at flow rates used in

cardiopulmonary bypass," in claim 30 is a relative term which renders the claim indefinite. The terms "higher rotational rate" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since the instantly claimed rotational rate "higher than" an undefined rotational rate is unclear, the claim is indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 7, 10, 12-14, 16, and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0110485 A1 to Stringer et al.

In the specification and figures, Stringer discloses the device as claimed by applicant. With regard to claim 1, Stringer discloses a blood handling system with gas removal comprising an axially elongate cylindrical shell or housing 40 defining several interior compartments that are contained within the chamber defined by the housing: gas collection plenum 50, central void 51, upper gas plenum 52, annular fiber bundle compartment 53, lower gas plenum 54, and pump space 55 (see FIG 3, paragraphs 0042-0045). The device further comprises an impeller 75 that is connected to drive unit or motor 32, a gas vent 46 located at the top of the chamber defined by housing 40 and

at a central axis of the shell or housing, a blood inlet port 41 affixed to the chamber defined by housing 40, and a blood outlet port 42 located at the radial periphery of the shell or housing (see FIG 3). While the illustration shows a filter material 59 between the impeller and the gas outlet, Stringer discloses that blood flows through the filter material 59 towards impeller 75, indicating that the two spaces on either side of the filter material 59 are in a single chamber. If they were in separate chambers, blood would not be able to flow from the gas outlet area to the impeller.

With regard to applicant's limitation that the chamber diameter is approximately constant between the blood inlet, blood outlet, and impeller, the Stringer device meets the limitation, since the diameter of the shell or housing 40 is illustrated as having similar diameters at pump space 55 and blood inlet 41. While blood outlet 42 is located in a portion of the device with a larger diameter than at pump space 55 and blood inlet 41, it is not dramatically out of line with the other diameters, creating a chamber of "approximately" constant diameter between the three elements.

With regard to applicant's limitation that the impeller is configured to directly rotate a volume of blood within the chamber, the Stringer device comprises a rotating impeller 75 that directly contacts the blood to move it through the apparatus (see paragraph 0061). A rotating impeller necessarily rotates a volume of fluid that flows past the impeller. Therefore, the impeller disclosed by Stringer directly rotates blood as claimed by applicant. Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the

blood and collect in the upper portion of the housing (see paragraphs 0058-0059). See also Stringer FIG3, as annotated by the Examiner, below.

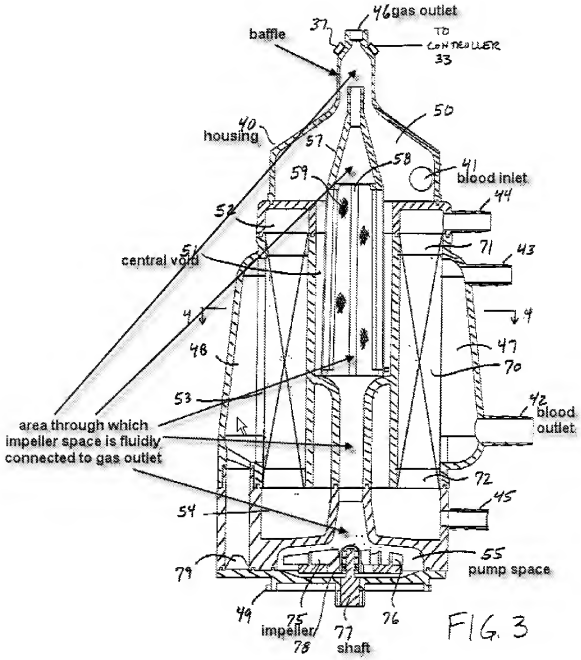

FIG. 3

With regard to claim 2, Stringer discloses that blood inlet 41 is located tangentially to the centerline of the housing or shell 40 (see paragraph 0046).

With regard to claim 3, Stringer illustrates that the gas outlet 46 is surrounded by a cylindrical, narrow portion of the housing, which acts as a baffle, directing flow therethrough (see Stringer FIG 3).

With regard to claim 4, applicant claims that the motor is electrically driven and that the motor and impeller are capable of rotating the impeller at a claimed RPM. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the motor disclosed by Stringer is capable of being electrically driven, and Stringer discloses that electrical lines may power the disclosed invention (see paragraph 0077).

With regard to claim 6, Stringer discloses that the gas vent 46 may be connected to a gas suction source 34, corresponding to applicant's claimed gas pump (see paragraph 0042).

With regard to claim 7, Stringer discloses a filter element 85 is disposed at the entrance to blood outlet manifold 47, which connects to blood outlet 42, meeting the limitations of the claims (see paragraph 0058).

With regard to claim 10, Stringer illustrates that blood inlet port 41 is located higher than blood outlet port 42 (see FIG 3).

With regard to claim 12, Stringer illustrates that gas outlet port 46 is located at the top of the housing 40, higher than the blood inlet port 41 and blood outlet port 42 (see FIG 3).

With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 and comprises a plurality of vanes 76 (see paragraph 0052).

With regard to claim 16, Stringer discloses that the gas removal port or vent 46 comprises a gas collection plenum 50 that collects or traps gas before venting, meeting the limitations of applicant's claim drawn to a gas trap (see paragraph 0046).

With regard to claim 24, Stringer discloses the shell, impeller, motor, vent, inlet, and outlet as claimed by applicant. Applicant further sets forth limitations drawn to the operation of the device. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that the impeller 75 is mounted on shaft 77 that is concentric with the axis of the shell, indicating that the impeller is capable of rotating as claimed by applicant, driven by motor or drive unit 32 (see paragraph 0052, 0061). Similarly, Stringer discloses that the device receives blood through inlet 41 from a patient via venous line 11 and delivers treated blood (including blood from which bubbles have been removed via gas removal system) to the patient through outlet 42 via arterial line 12 (see paragraph 0039, 0042).

The Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). While the illustration shows a filter material 59 between the impeller and the gas outlet, Stringer discloses that blood flows through the filter material 59 towards impeller 75, indicating that the two spaces on either side of the filter material 59 are in a single chamber. If they were in separate chambers, blood would not be able to flow from the gas outlet area to the impeller. As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to applicant's limitation that the impeller is configured to directly rotate a volume of blood within the chamber, the Stringer device comprises a rotating impeller 75 that directly contacts the blood to move it through the apparatus (see paragraph 0061). A rotating impeller necessarily rotates a volume of fluid that flows past the impeller. Therefore, the impeller disclosed by Stringer directly rotates blood as claimed by applicant. Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal

force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059).

With regard to applicant's limitation that the chamber diameter is approximately constant between the blood inlet, blood outlet, and impeller, the Stringer device meets the limitation, since the diameter of the shell or housing 40 is illustrated as having similar diameters at pump space 55 and blood inlet 41. While blood outlet 42 is located in a portion of the device with a larger diameter than at pump space 55 and blood inlet 41, it is not dramatically out of line with the other diameters, creating a chamber of "approximately" constant diameter between the three elements.

With regard to claim 25, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 (see paragraph 0052). With regard to the manner of rotation, Stringer illustrates the impeller as contained entirely within shell or housing 40 (see FIG 3), indicating that the magnetic coupling between the impeller 75 and drive unit 32 is capable of rotating the impeller through the housing or shell 40, meeting the limitations of the claim.

With regard to claims 26 and 27, Stringer discloses that the apparatus is intended to be part of an extracorporeal bypass system, indicating that the blood inlet port 41 and blood outlet port 42 are connected to blood handing system 30 (see FIG 1, paragraph 0038).

With regard to claims 28 and 29, applicant further sets forth limitations drawn to the operation of the device and the movement of blood therethrough. Such statements

are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). Furthermore, Stringer discloses that blood exits the device via blood outlet manifold 47 and blood outlet 41, located away from the gas collection plenum 50, minimizing gas/blood contact. Since Stringer suggests that the disclosed device is capable of operating as claimed by applicant, it meets the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 5 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,840,735 to Yaegashi et al.

In the specification and figures, Stringer discloses the apparatus substantially as claimed by applicant with the exception of the operational speed of the impeller. Such a statement of the use of the device is generally does not differentiate the instantly

claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, however, Stringer is silent as the rotational speed of the impeller.

With regard to claim 5, centrifugal blood pumps that operate at high rotational speeds, such as the pump disclosed by Yaegashi, are well-known in the art of extracorporeal blood circulation. In particular, Yeagashi discloses a centrifugal blood pump apparatus with an impeller 21 that may be operated at speeds from less than 500 rpm to more than 1400 rpm, falling within applicant's claimed range (see FIGS 4, 7). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the pump disclosed by Yaegashi, which rotates the impeller at the speeds claimed by applicant, in the apparatus disclosed by Stringer, since such high-speed centrifugal blood pumps are well-known in the art, as demonstrated by Yaegashi.

With regard to claim 30, applicant claims a "means for adding," a "means for impelling," a "means for venting," and a "means for removing." The language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification provides reasonable support for the "means for" limitations above, indicating that the structure that performs the claimed functions comprise a blood inlet, an impeller, a gas vent, and a blood outlet.

Stringer specifically discloses a blood treatment device with a housing or shell 40, blood inlet 41, impeller 75, gas vent 46, and blood outlet 42, thereby meeting the structural limitations of the claim. With regard to applicant's recitation of the action of the impeller, the Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). While the illustration shows a filter material 59 between the impeller and the gas outlet, Stringer discloses that blood flows through the filter material 59 towards impeller 75, indicating that the two spaces on either side of the filter material 59 are in a single chamber. If

they were in separate chambers, blood would not be able to flow from the gas outlet area to the impeller.

With regard to applicant's "means for directly impelling... to a higher rotational rate than is possible by tangentially injecting blood into the chamber at flow rates used in cardiopulmonary bypass," Stringer discloses rotating impeller 75 that directly contacts the blood to move it through the apparatus (see paragraph 0061). A rotating impeller necessarily rotates a volume of fluid that flows past the impeller. Therefore, the impeller disclosed by Stringer directly rotates blood as claimed by applicant. Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059).

Although it is the position of the Examiner that applicant's claimed "higher rotational rate" limitation is indefinite, the Examiner is interpreting that "higher rotational rate" to correspond to applicant's disclosed rotational rates of 100-10,000 rpm. Stringer is silent with regard to the rotational speed of the disclosed impeller 75. Centrifugal blood pumps that operate at high rotational speeds, such as the pump disclosed by Yaegashi, are well-known in the art of extracorporeal blood circulation. In particular, Yeagashi discloses a centrifugal blood pump apparatus with an impeller 21 that may be operated at speeds from less than 500 rpm to more than 1400 rpm, falling within applicant's claimed range (see FIGS 4, 7). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the pump

disclosed by Yaegashi, which rotates the impeller at the speeds claimed by applicant, in the apparatus disclosed by Stringer, since such high-speed centrifugal blood pumps are well-known in the art, as demonstrated by Yaegashi.

With regard to applicant's limitation that the chamber diameter is approximately constant between the blood inlet, blood outlet, and impeller, the Stringer device meets the limitation, since the diameter of the shell or housing 40 is illustrated as having similar diameters at pump space 55 and blood inlet 41. While blood outlet 42 is located in a portion of the device with a larger diameter than at pump space 55 and blood inlet 41, it is not dramatically out of line with the other diameters, creating a chamber of "approximately" constant diameter between the three elements.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,264,601 to Jassawalla et al.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of the blood outlet extending tangentially from the housing or shell of the device.

Jassawalla discloses a ventricular assist device with a pumping portion that comprises an inlet and outlet to move blood through the treatment device. The inlet and outlet conduits 24, 26 and ports 54, 60, are both located tangentially from the cylindrical pumping chamber 20 (see column 7, lines 51-67). The tangential orientation of the ports 54, 60 are selected to most efficiently fill and evacuate the chambers of the pumping device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the blood outlet of the Stringer device in a

tangential orientation to the housing as disclosed by Jassawalla in order to provide efficient filling and evacuation of the chambers of the treatment device, as taught by Jassawalla (see column 7, lines 51-67).

10. Claims 9 and 15 are is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,769,871 to Yamazaki.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of an antithrombogenic coating and a smooth impeller surface.

Yamazaki discloses a blood pump that circulates a patient's blood extracorporeally and prevents thrombus formation with an antihrombogenic coating made of a phospholipids bilayer and a small surface roughness. The coating is located on all surfaces that come into contact with the blood to reduce thrombus formation (see column 2, lines 5-30). The smooth impeller surfaces provide further thrombus suppression since blood will flow smoothly through the pump device (see column 3, lines 1-13). Therefore, it would have been obvious to one having ordinary skill in the art to provide the blood treatment and pumping device disclosed by Stringer with an antithrombogenic coating and smooth impeller surfaces as disclosed by Yamazaki, in order to prevent thrombus formation and allow long term deployment of the pump, as taught by Yamazaki (see column 2, lines 23-28).

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 5,823,987 to Elgas et al.

In the specification and figures, Stringer discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of placing the blood inlet lower than the blood outlet. Elgas discloses an extracorporeal blood treatment device with a blood inlet 30 at the bottom of the device and a blood outlet 32 located above the inlet (see FIG 4). The position of the inlet and outlet provide a blood flow path that minimizes trauma to the blood cells and provides improved blood flow designed to minimize recirculation and stagnant areas (see column 2, lines 19-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to reverse the position of the blood inlet and outlet disclosed by Stringer in order to provide a blood path that minimizes recirculation and stagnant areas, as taught by Elgas (see column 2, lines 19-25).

Response to Arguments

12. Applicant's amendment and arguments filed 30 November 2007 have been entered and fully considered but they are not persuasive.

13. Applicant argues that the instantly claimed invention comprises a chamber comprising an axially elongate cylinder with no restriction or constriction between the blood inlet, blood outlet, and impeller as well as no separation between the gas vent and the impeller. However, applicant's arguments are narrower than the language of the claims. Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant does not specifically set forth that the apparatus comprises a single chamber nor that there are no walls, compartments, or filters that obstruct the chamber between the blood inlet, outlet, impeller, and gas outlet.

14. Applicant further argues that "the definition of a cylinder requires straight sides." The Examiner respectfully notes that applicant claims a "cylindrical shell," not a shell comprising a cylinder. It is the position of the Examiner that a "cylindrical" item may have the general form of a cylinder, which has parallel sides, but is not required to have the exact dimensions of a cylinder. This interpretation is supported by applicant's claim limitations reciting a chamber with an "approximately" constant diameter. A cylinder must have an exactly constant diameter. A cylindrical shell may comprise the general properties of a cylinder, which may include "approximately" constant diameter sections.

15. Applicant argues that the Stringer device is not capable of directly rotating the blood at a much higher rotational rate than could a passive tangential inlet line. While Stringer is silent as to the rotational rate of the blood, applicant has failed to define the range that makes up the "much higher rotational rate."

The Examiner has amended her rejection to include a teaching of applicant's disclosed rotational rates, postulating that it would have been obvious to one having ordinary skill in the art at the time of invention to add a high-speed pump as disclosed in the art to the apparatus disclosed by Stringer in order to create the rotational speeds disclosed by applicant. Nonetheless, the Examiner wishes to address portions of applicant's argument pertinent to the instant rejection

Applicant's arguments cannot take place of factually supported objective evidence in the record. Rebuttal evidence showing unexpected results may be based on evidence, not argument or speculation. See MPEP 2145. Applicant's arguments that the Stringer device (or the combined Stringer and Yaegashi reference) are incapable of generating the claimed rotational speeds are not supported by factual evidence in the form of, for example, test results or peer-reviewed journal articles. As such, Applicant has not provided any objective evidence showing that the instantly claimed invention shows an unexpected improvement over the prior art.

Applicant argues that the impeller disclosed by Stringer is not located in the same chamber where the air is removed from the blood. However, Stringer's FIG 3 shows a filter material 59 between the impeller and the gas outlet, but Stringer discloses that blood flows through the filter material 59 towards impeller 75, indicating that the two spaces on either side of the filter material 59 are in a single chamber. If they were in separate chambers, blood would not be able to flow from the are of the gas outlet to the impeller.

16. It is the position of the Examiner that the limitations of the dependent claims are met by the combinations of Stringer with the other prior art of record as set forth above.

17. Applicant's arguments, with respect to the 35 USC 103 rejections over Stringer and Yamazaki have been fully considered and are persuasive. The rejections have been withdrawn.

18. The letters filed under an attempt to invoke 37 CFR 1.132 affidavit consideration, filed 30 November 2007, are insufficient to overcome the rejection of the pending claims

based upon the rejections over Stringer as set forth in the last Office action for several reasons, enumerated below. The Examiner is considering the letters as attempts to provide 37 CFR §1.132 declarations to contest whet the primary reference teaches or shows.

First, the submitted letters are not properly submitted as affidavits or declarations under 37 CFR § 1.132, since there is no statement by the declarant that he or she is aware that willful false statements in the letter are punishable by fine, imprisonment, or both. See 35 USC § 25.

Second, there is no CV or resume to establish the declarants' alleged expertise or statement that the declarants are disinterested third parties. See MPEP § 716.01(c)(III).

Third, the letters provided by applicant do not satisfy the criteria for overcoming a rejection based on affidavit or declaration evidence. Specifically, the declarations refer only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the invention referred to by the declarants is commensurate in scope with the claims. See MPEP § 716. Additionally, the declarations vaguely suggest that the instant invention solves a long-felt need in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. Finally, the letters provide mere opinions as to the

effectiveness of the prior art devices and do not address the issue at hand: that is, what the prior art does or does not teach with respect to what is claimed by applicant.

In conclusion, although the letters provided by Applicant fail to qualify as proper affidavits or declarations under 37 CFR § 1.132, the Examiner has considered the statements therein with regard to the patentability of the instantly claimed invention. It is the position of the Examiner that the letters provided by Applicant fail to set forth properly formatted opinion evidence or persuasive objective evidence that establishes the novelty or non-obvious nature of the instantly claimed invention over the prior art. Accordingly, it is the position of the Examiner that the instantly claimed invention is unpatentable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Patent Examiner
Art Unit 3761
14 February 2008

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761